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Special Issue:
Laboratory Automation in Asia!
Detailed Reports on What's Hot...

From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Retrospective on Lab Automation in Japan

DO YOU REMEMBER BACK TO THE FIRST TIME YOU HEARD NEWS that national lab companies like **MetPath, Inc.** and **SmithKline Beecham Clinical Laboratories** (SBCL) were going to install full automation into their laboratories? It was back in 1991-1993 when this talk began filtering across the laboratory industry. This was the start of TLA (total laboratory automation) as a competitive threat. It was believed that commercial laboratories which didn't adopt TLA would be at a severe competitive disadvantage to those lab companies which did.

Fast forward to 2006. Surprisingly, the nation's largest labs have been slow to utilize TLA. In fact, two of the three TLA systems installed at MetPath and SBCL labs by 1996 were turned off and no new ones installed in their place. During the past decade, it was health system and hospital labs which implemented full TLA solutions, although their numbers are limited.

Let's take another step down memory lane. Do your remember conversations you had with vendors and proponents of TLA during the years between 1993 and, say 2000? Do you recall the "role model" for TLA that was held up as the validation of TLA? Give yourself an "A" for total recall if your answer was laboratories in Japan. The drumbeat of diagnostic firms and TLA advocates was consistent and continual: "TLA is a success in Japan! Japanese labs handle huge volumes of specimens with few employees. This works extremely well in Japan and laboratories in the United States will equally benefit when they buy TLA technology and put it to work in their laboratories."

My reason for dredging up these memories is because of a fascinating thing that happened at the Fifth International Conference on Laboratory Automation and Robotics, conducted in Seoul, Korea just three weeks ago. THE DARK REPORT was there to present and to participate in the activities. Editor Robert Michel shares his experiences, insights, and observations in this special issue. What caught my attention is his report on the comments of Jutaro Tadano, M.D., Ph.D., who is deeply respected in Japan for his seminal work in specific aspects of laboratory automation.

In his prepared remarks, Dr. Tadano looked back on 25 years of process innovation in Japanese laboratories. His conclusion—and his recommendation—offer unique wisdom to pathologists and lab directors. I won't spoil the surprise. You can read it for yourself on pages 15-17. TDR

Seoul, Korea Hosts Lab Automation Meeting

Held every second year, it is the showcase for advanced applications in lab automation

CEO SUMMARY: It was the fifth "International Conference on Laboratory Automation and Robotics." Over the past decade, this meeting, started by the pioneers of clinical laboratory automation, has been the major forum to meet and discuss advances in all aspects of automation. This conference is not widely-known in North America or Europe, although the conference always features speakers from these regions.

EVERY SECOND YEAR, a laboratory meeting takes place in the Far East which gets little attention in the United States and Canada. It is the "International Conference of Laboratory Automation and Robotics."

This year's event was held on April 13-14 in Seoul, Korea. It attracted more than 377 attendees from 15 countries and was supported by 17 vendors. It was the fifth automation conference and featured speakers on laboratory automation and robotics from Japan, Korea, China, Singapore, Australia, United States, Germany, Finland, and The Netherlands.

THE DARK REPORT was there, both to speak on the economic and other forces influencing the adoption of laboratory automation and to participate in the full event, which included site visits of three Korean laboratories. It was an opportunity to learn about lab automation's past and present.

As to the present, this year's meeting showcased many of the latest technologies and products for laboratory automation. A surprising amount of sophisticated instruments and solutions are available in Asian countries, but not yet sold in the United States.

As to the past, the story of the laboratory automation and robotics conference is closely linked to the evolution of laboratory automation. Most of the attendees were from Korea, Japan, and other Far Eastern countries and have been enthusiastic pioneers for laboratory automation, some starting as early as 1980.

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R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $11.90 per week in the US, $12.50 per week in Canada, $13.65 per week elsewhere (billed semi-annually).

The knowledge gained about the past and present of laboratory automation in the Far East will be both fascinating and useful to pathologists and laboratory managers in the United States and Canada. That's because today's laboratory automation solutions are directly linked to the early development work done in Japan in the decade of the 1980s.

Three Intelligence Briefings

The easiest way for THE DARK REPORT to share the knowledge and insight gained from this experience is to divide it up into separate intelligence briefings, organized around three topics. First will be highlights from some of the more intriguing presentations delivered at the conference.

The second briefing will cover what was seen during site visits to three laboratories in Seoul. The third and final briefing will center around the remarks made by Jutaro Tadano, M.D., Ph.D., who is a respected early pioneer in laboratory automation from its original roots in Japan. Dr. Tadano was a major contributor to laboratory automation in Japan from its earliest days. He offered a 25-year retrospective on the subject, along with a surprising assessment of the consequences to laboratories in Japan from their automation initiatives.

Do More With Less

What made this meeting particularly interesting is the approach that many laboratories in Asia take toward automation, compared to the United States. Speaking generally, automation solutions are viewed in the context of how such changes will affect patients and patient care—while also improving productivity and reducing costs in the laboratory. In the United States, primary motivations for automation are often to cut costs or as a substitute for labor, allowing medical technologists in the lab to be shifted to higher value duties.

First Time in Korea for the Cherry Blossom Symposium

THIS YEAR WAS THE FIFTH "International Conference of Laboratory Automation and Robotics." It was the first time that the conference was conducted outside of Japan.

The first conference took place in 1998. It was organized by Masahide Sasaki, M.D. Ph.D., and was held in Kochi, Japan. Dr. Sasaki, who died last year, was Professor of Clinical Laboratory Medicine at **Kochi Medical School** in Nankoku City, Kochi, Japan. He is credited with implementing the first automation system in a clinical laboratory during the early 1980s.

This conference is held every second year. In 2000, the second conference was held in Karatsu. It then moved to Hamamatsu in 2002, and to Tokyo in 2004. It is also called the "Cherry Blossom Symposium" because, in early spring, the cherry blossoms are in abundance throughout Japan, Korea, and other Asian countries.

Each Cherry Blossom Symposium is hosted and produced by pathologists and laboratorians from the host city and region. For Seoul, Korea, the conference was chaired by Jin Q. Kim, M.D., Ph.D., Chairman and Professor, Department of Laboratory Medicine at **Seoul National University Hospital**. The Korean laboratory community staffed the organizing and advisory committees. Dr. Kim proved to be a gracious host and was quite effective at making all the delegates feel at home in Seoul, regardless of how far they traveled to attend the program.

This year's conference was well-organized and chock-full of interesting presentations. There was also an exhibit hall where manufacturers showed their latest laboratory automation products.

The Sixth International Conference on Laboratory Automation and Robotics will move back to Japan. It will be held in the spring of 2008 and will return to Kochi, site of the first conference organized by Dr. Sasaki in 1998. It is a meeting that pathologists and laboratory managers with a keen interest in automation are likely to find valuable.

Conference Speeches Offer Useful Insights

Asian labs approach automation in ways that are different from North American labs

CEO SUMMARY: There is an interesting dichotomy between Asia and North America. The same problems and challenges exist in both regions—declining reimbursement and budgets, labor force issues, and the need to spend more for new diagnostic technology. Yet laboratories in both regions see automation from different perspectives. Here's a summary of several presentations given at the Seoul conference.

WITH SPEAKERS FROM NINE COUNTRIES talking about a broad range of topics, the laboratory automation and robotics conference offered a unique look at this field.

However, for many reasons, the strongest emphasis was given to laboratories from the host country, Korea, and from Japan, where laboratory automation was first developed in a serious way. It was obvious that laboratories in both Japan and Korea have gone further with laboratory automation than most laboratories in countries like the United States, Canada, the United Kingdom, and Australia.

Challenges Are The Same

Moreover, the challenges and themes discussed by speakers would ring true with pathologists and laboratory managers here in the United States. For example, the conference's lead-off speaker was Eun Hee Lee, M.D., Ph.D., who is Vice President at **Green Cross Reference Laboratory**, located in Seoul, Korea.

At the start of her presentation, Dr. Lee observed that "unlike most businesses in Korea, clinical laboratories are not free to increase their prices in response to price increases. That's because the government health program in Korea largely dictates the prices paid for laboratory testing."

Green Cross Laboratory is a for-profit lab company that is a true reference/esoteric laboratory serving Korea. Specimens from hospitals and some physician clinics are referred to it each day. "Our workload [specimen volume] increased at the rate of 8% per year in recent years," noted Dr. Lee. "By 2004, we had reached the maximum workload and could not process any more tests with our existing, stand-alone instrument systems."

Confronted with increased volume, rising costs, and tight reimbursement, Green Cross opted for laboratory automation and the **Bayer** ADVIA Labcell was its solution. Once implemented, this automation not only resolved the throughput constraints of the existing laboratory, but

gave Green Cross additional capacity to meet the increases in specimen volume projected for the coming years.

Dr. Lee noted that, after implementation, the number of tests per FTE increased from 1,250 to 1,600. Because of the shift to primary tube use and the reduction of aliquots, the number of tubes handled in the lab each day was reduced by 40%.

Following the conclusion of the conference, THE DARK REPORT was able to visit the Green Cross Laboratory. More comments about the site tour and this laboratory can be found on pages 11-14.

Open vs. Closed Systems

One of the interesting insights which emerged is that "open system" automation solutions are often found in laboratories in Asia. For example, Yuanchun Zang, M.D., Director of Laboratory Medicine at the **China-Japan Friendship Hospital** in Bejing, China, discussed the design and implementation of a pre-analytical system in his laboratory.

According to Dr. Zang, at the end of 2005, there were only seven laboratories in China with significant automation. Major vendors to date have been **A&T**, **Beckman Coulter Corporation**, and **Olympus Corporation**. Dr. Zang's laboratory is implementing a pre-analytical automation system from A&T which connects to two **Abbott** Architect 1200s and a **Hitachi** 7600-PP.

Large hospitals, at 1,000 beds or more, are common in Asia. Further, these hospitals are generally connected to a related outpatient clinic of comparable size. For that reason, the hospital laboratory is frequently handling significant volumes of specimens. This is one reason why these laboratories were motivated to look at automation years ahead of labs in North America or Europe, for example.

An example of automation in a super-sized hospital is the **Asan Medical Center and University of Ulsan College of Medicine**, located in the eastern suburbs of Seoul, Korea. It is adding 400 beds to its existing 2,200-bed facility. Each day it serves 8,000 outpatients.

Large Laboratory Operation

The laboratory is large. During 2005, it performed 25 million tests. It handles 3,300 specimens and 2,300 specimens per a day in chemistry and hematology, respectively.

In his remarks, Won-Ki Min, M.D., Ph.D., Professor and Head of Clinical Chemistry for the Laboratory Department at Asan Medical Center, stated that the laboratory's prime focus was to support the outpatient clinic's goal of "same day" service. "The objective is for patients to visit their physician with test results as soon as possible in the same day that the sample was collected," stated Dr. Min. "This was a change from the existing situation, which required the patient to come in for specimen collection several days before his or her visit with the doctor."

Dr. Min noted that the laboratory was only one contributor to this goal. Efforts to reduce turnaround time are also under way in other diagnostic services at this facility, such as MRI, EKG, and endoscopy.

Same Day Reflexive Tests

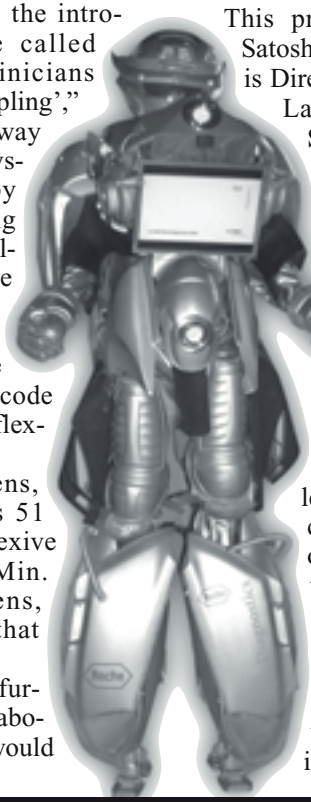
To achieve faster turnaround time in support of same-day outpatient service, laboratory automation was only a fourth-phase solution. "We named our project 'reflexive tests for physicians without additional sampling'," explained Dr. Min. "We organized the laboratory so that routine results would all be reported to physicians by 11 a.m.," he said. "That was stage one. Stage two was the implementation of a new information system.

"With the information system in place, stage three was the introduction of what we called 'reflexive tests by clinicians without additional sampling'," Min continued. "One way the new information system supports this is by prompting the ordering physician to the possibilities of specific reflexive tests. The system allows the physician to select these reflexive tests and produce bar code labels for same-day reflexive tests.

"For SST specimens, our laboratory offers 51 possibilities for a reflexive test," explained Dr. Min. "For EDTA specimens, there are three tests that can be reflexed."

Stage four will be further automation in the laboratory. "By 2010, we would like to have conventional laboratory automation in place, supplemented by the added functions of level detectors to determine if enough sample volume exists, refrigerated storage dedicated to storage of samples for reflexive testing, and management software for this system," concluded Dr. Min.

Not every presentation was focused on automation of work processes in the laboratory. One fascinating presentation involved automation of hospital infection control through the use of the electronic medical record (EMR).



"ROBO ROCHE"

What's a conference on laboratory automation and robotics without a robot! This big fella, about eight foot tall, could be found guarding the Roche Diagnositics exhibit. He delighted the crowd. After all, Asians are known to be attracted to the very newest in technology and gadgets. No word on when you may be able to purchase a "Robo Roche" to work in your lab.

Reducing Infections

This presentation was made by Satoshi Kimura, M.D., Ph.D., who is Director of the Central Clinical Laboratory at the 661-bed **Showa University Northern Yokohama Hospital** in Yokohama City, Japan. "Surveys of Japanese patients reveal that long waiting time is their major complaint. The second biggest source of dissatisfaction is hospital-acquired infections," observed Dr. Kimura.

"To address this problem, we developed four new capabilities to interact with our EMR," he said. "First, we built a warning/advisory function into the EMR. Each patient name is coded in a color that represents one of four infection control precaution levels. This is to alert physicians and hospital staff about which patients have pathogenic agents and which situations might lead to transmission of such pathogens. As part of this function, the clinical laboratory sends information about detected micro-organisms directly to the EMR.

Color Codes For Risk

"The color blue is used for patients with active tuberculosis," stated Dr. Kimura. "Green stands for patients with MRSA (methicillin-resistant *S. aureus*) and red represents active viral hepatitis.

"Our second enhancement is an automatic, real-time survey for hospital

Sonic Uses Software To Automate Processes

ONE OF THE MORE INTRIGUING PRESENTATIONS involved the use of software to write and apply rules that prevent errors in the lab testing process. It was presented by Alan Lloyd, MB.ChB, M.Med, Chief Systems Officer of **Sonic Healthcare, Ltd.** of Sydney, Australia.

"We are using software to guide decisions in three functions," explained Lloyd. "First, we developed a decision support product that interacts with the physician management systems in doctors' offices. This allows us to suggest appropriate tests based on the patient's circumstances.

"Second, we have a sophisticated capability for workstation routing within our lab," continued Lloyd. "For example, 70% of our specimens go from accessioning directly to analyzers without aliquoting. Further, this system won't let a tube be accepted at an incorrect workstation.

"Third, we developed an Episode Expert System that guides many decisions within our laboratory," he noted. "This is rules-based, is triggered by specific events, and checks all the parameters affecting the situation to determine what response will appropriately correct the situation."

This system uses pattern recognition to identify opportunities for rules and define those rules. "Information used to develop rules based on pattern recognition allows the system to handle, automatically, about 80% of the common error patterns," observed Lloyd. "The other 20% are more complex and can be handled by pathologists."

infections," continued Kimura. "The EMR automatically counts the number of patients with infectious diseases. Statistics on control levels are built into the system.The infection control team then monitors the results and trends. Where warranted, they take action.

"The third feature we built into the EMR is an automatic survey for any patterns of antibiotic resistance," he noted. 'The EMR can present a single table which shows microbiology infection control patterns. Sensitivity to antibiotics is shown in this table.

Monitoring Antibiotics Use

"Our fourth feature is an automatic survey for antibiotics usage," added Kimura. "Because over-prescribing of antibiotics is a factor in the development of multi-drug-resistant bacteria, we want to control use of antibiotics.

"Built into the EMR, this function monitors antibiotics usage by all the patients in our hospital. When the system detects excessive use of antibiotics, it flags the infection control team so it can advise the attending physician."

Dr. Kimura did not provide specific data about outcomes and how this effort has changed the base line numbers of hospital-based infections. He did observe that, since adding these four functions to the EMR, there are fewer major outbreaks in his hospital.

Another fascinating topic was a project in Japan to harmonize and standardize laboratory tests across all laboratories within the Fukuoka Prefecture, an area with a population of about five million people. The presentation was made by Naotaka Hamasaki, M.D., Ph.D., Professor of Clinical Chemistry and Laboratory Medicine at **Nagasaki International University** in Nagasaki, Japan. In simplest terms, during the mid-1990s, baseline data was developed, using data from several large labs in the prefecture. The resulting standardization parameters were

adopted by 97% of the institutions in Fukuoka Prefecture. These standards are updated every five years.

The project centers around "22 clinical chemistry analytes and serum protein constituents (IgG, A, M, C3, C4) in Fukuoka." Dr. Hamasaki noted that "there is a daily survey of the reference laboratories and a monthly survey of all regional laboratories participating in the project.

"In the daily survey, 23 out of 27 analytes are within the allowable bias of $0.25B_A$," he said. "In the monthly survey, 13 out of 27 analytes were within the allowable bias of $0.25B_A$."

"One outcome of this project is that the inter-laboratory variation has decreased, mainly in clinical chemistry measurements," continued Hamasaki. "This has accomplished the primary aim of this project.

According to Hamasaki, the long term goal is to make this a national laboratory standardization effort. The parallels to this project and developments in the United States are intriguing.

"We are planning to increase the number of measured analytes and also expand the regions participating in this standardization project," he said. "We now also use the Internet to allow the standardization project to work and report in real time."

According to Hamasaki, the long term goal is to make this a national laboratory standardization effort. The parallels to this project and developments in the United States are intriguing.

In the United States, there are strong efforts to get all clinicians to consistently follow recommended practice guidelines. The goal is to reduce variability in care. As this happens, it is feasible that the American healthcare system might want more uniformity in the laboratory test results which would populate the patient's universal electronic medical record (EMR).

Reduce Variation In Care

This could lead to calls for all laboratories in a region to standardize their tests and harmonize laboratory data. Seen from this perspective, the project to harmonize and standardize laboratory tests across all laboratories within the Fukuoka Prefecture could be an early look at something which might happen in the United States in future years.

As the summaries of these six presentations demonstrate, there is a wide variety of innovation occurring in different countries. In some cases, these projects are ahead of what is happening in North America. Certainly some of these innovations are a product of the cultural environment, allowing these laboratories to do things that would be difficult to implement in the United States.

For example, imagine how difficult it would be in this country to have all the laboratories in states like Arizona, Maryland, and Minnesota (each with a population of about five million people like Fukuoka), to agree to standardize tests and harmonize lab test data. Yet that is what laboratories in the Fukuoka Prefecture have achieved! And this project is already in its eleventh year. TDR

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Different Healthcare System – Different Approach to Phlebotomy:

In Korea, inpatients and outpatients are served at automated site

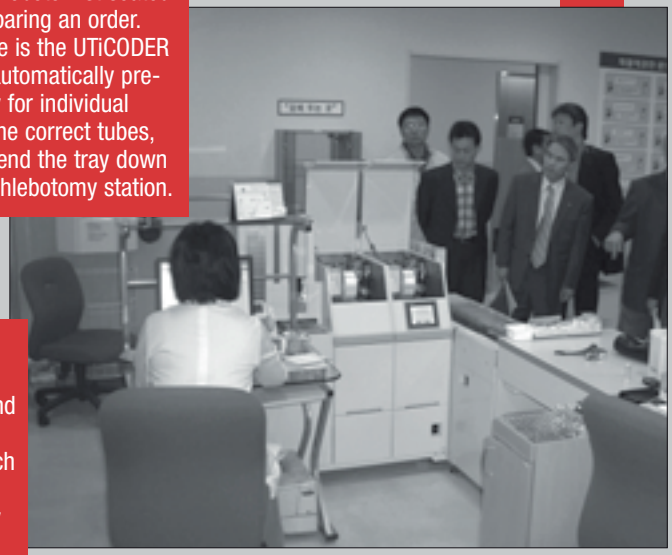
During our site visit to Konkuk University Hospital in Seoul, Korea, we had an opportunity to see an automated phlebotomy site in operation. In Korea, hospitals and outpatient clinics are located within the same facility. Konkuk University Hospital has 710 beds and serves 2,500 outpatients each day. The laboratory performs about 250,000 tests per month and draws 350 patients per day. The extensive use of automation in this phlebotomy station has no counterpart in the United States.

1

Picture 1: This view shows the waiting chairs a few feet from a long counter where three phlebotomists can work at the same time. A reception station is located in the back left corner. Number signs atop the white poles signal patients when it is their turn. In Asia, the need for privacy and personal space is less than in North America. The arrangement of this drawing facility reflects that cultural difference.

Picture 2: The phlebotomist seated at the computer is preparing an order. The system shown here is the UTiCODER 2107 from IDS. It will automatically prepare a phlebotomy tray for individual patients. It will select the correct tubes, apply bar codes, and send the tray down a track to the correct phlebotomy station.

2



Picture 3: This view shows how the automated tray prep and loader connects to the track which carries each patient-specific tray to the correct phlebotomy station. The transport line runs under the counter. Note, at top, the sign which alerts patients that their number has been called.

3

Picture 4: Here is a closer view of the phlebotomist stations. The openings in the counter which allow access to the transport line are visible. Specimens are sent into the main laboratory using a transport line which is at the left rear of this picture, behind the computer screen. Within moments after this picture was taken, a patient arrived to have blood drawn. The procedure was done in front of the tour, and neither the phlebotomist nor the patient seemed concerned by that situation.

4

Tour of Korean Labs Has Plenty to Teach

Greater willingness to use automation to boost productivity and improve quality

CEO SUMMARY: Faster turnaround times and better quality seem to be some common motivations for installing automation in the three Korean labs visited by THE DARK REPORT last month. All the laboratories were extra clean and neat, relative to most North American labs. Each of the laboratories visited reports a high degree of satisfaction with the performance of its laboratory automation solution.

ONE HIGHLIGHT OF THE TRIP TO KOREA was a day spent visiting three laboratories in the Seoul area. Two were hospital labs and one was a national reference/esoteric lab.

There is no better way to understand how a laboratory is organized and operated than to visit it during operational hours. This was true of the site visits to these three Korean laboratories. Site visits allow one to see many key details that would probably not be mentioned during a speech or similar presentation.

First stop on the tour was the laboratory at **Konkuk University Hospital** in Seoul. The host was Yeomin Yoon, M.D., Ph.D., Chief and Professor, Department of Laboratory Medicine. Konkuk is a 750-bed hospital that is expanding to 850 beds. The population of Seoul is about 12 million people and the region is served by 13 university hospitals.

The hospital facility is new and boasts an unusual feature. It is the only hospital in Seoul that is directly connected to the subway system. People can get off a train and walk right into the hospital.

Since the hospital serves 2,500 outpatients per day, this is an attractive feature. In Korea, outpatient clinics and hospitals are operated together. These patients are all served by the hospital laboratory. So the combined volume of inpatient and outpatient testing is often substantial.

TLA In The Laboratory

"This laboratory performs about 250,000 tests per month," noted Dr. Yoon. "The TLA [total laboratory automation] system peforms about 26% of this testing and the hematology line accounts for 12%."

The laboratory has automation in several areas. The phlebotomy center adjacent to the laboratory has an automated system for bar code labeling and tray delivery to the phlebotomists. *(See pages 9-10.)* Once collected, a system transports the specimens directly into the laboratory.

Here a pre-analytical modular system (PAM) takes over. Specimen processing is automated, including an input

buffer module, automatic centerfuge, destopper, on-line aliquoter, barcode labeler, and output buffer module.

Chemistry and immunoassay analyzers are connected directly to the PAM. These include two **Toshiba** 200FRs, a **Bayer** Centaur, and a **Roche** E170. "Once a specimen is received and registered, the system takes about 14 minutes to produce aliquot tubes," explained Yoon. "On average, it takes 30 minutes to produce chemistry results and 40 to 60 minutes to produce immunoassay results."

As specimens finish in this section, there is an automated system for storage and retrieval. Konkuk University Hospital has a paperless information system and the laboratory uses an LIS from **AGK**, a Korean company. Its point-of-care network is interfaced directly with the LIS.

Laboratory Staff

The laboratory occupies 850 square meters, about 9,200 square feet. It is a new facility and immaculately clean. "Staff consists of three physicians, 27 technical FTEs and two assistants," said Yoon. "On the day shift, our technical staff works 12-hour shifts. We staff four technical people at night."

Next stop on the laboratory tour was **Seoul National University Bundang Hospital**. It is a new hospital, opened in May 2003. It is designed to perform transplants and serve the growing geriatric needs of the population. It has 833 beds and serves over 3,000 outpatients per day.

Host for this tour was Junghan Song, M.D., Ph.D., Assistant Professor of Clinical Chemistry and Biochemical Genetics. This laboratory performs about 500,000 tests per month. Dr. Song did say that his lab counts a CBC (complete blood count) as five tests.

The Bundang Hospital laboratory has an extensive TLA system, designed and built by **A & T Corporation**. This

Automation Summary For Three Site Visit Labs

THREE LABORATORIES IN SEOUL, KOREA hosted site visits. Each was using automation in different ways. Here's a summary of the automation seen at each site.

KONKUK UNIVERSITY HOSPITAL:

Hitachi PAM System–connected system

- Centerfuge unit
- Decapping unit
- On-line and off-line aliquotting unit
- Two chemistry analyzers (Toshiba 200-FR)
- Two Immunoassay analyzers (Roche E170, Bayer Centaur)

Sysmex hematology Automation System–connected system

- Two hematology analyzers (Sysmex XE-2100)
- One slide maker (Sysmex SP1000i)

SEOUL NATIONAL UNIVERSITY BUNDANG HOSPITAL:

A&T CLINILOG System–connected system

- Centerfuge unit
- Decapping unit
- On-line aliquotting unit
- Three chemistry analyzers (Toshiba 200-FR, A&T 502X)
- Two Immunoassay analyzers (Roche E170, Abbott Architect i2000)
- Two electrolyte analyzers (A&T EA07)

Sysmex hematology Automation System–connected system

- Two hematology analyzers (Sysmex XE-2100)
- Two slide makers (Sysmex SP1000i)

GREEN CROSS REFERENCE LAB:

Bayer ADVIA LabCell Modular System–connected system

- Sample manager, three units
- Three chemistry analyzers (ADVIA 1650, ADVIA 2400)
- Three immunoassay analyzers (ADVIA Centaur 3)

company now sells in the United States and maintains an office in Irvine, California. In Asia, A & T Corporation has a major presence. It has automated systems in more than 100 laboratories throughout the Pacific Rim.

Bundang's TLA starts with pre-analytical processes. Sequentially, there is a start stocker, on-line centerfuge, decapper, and aliquoter. Connected to the automated line, in order, is an **Abbott** Architect i2000, a Roche Elcsys, two Toshiba 200Frs, and a rerun buffer. At the end is a terminal stocker. Hematology is handled separately with an integrated **Sysmex** automation line. There was a separate stat lab, which included two **Ortho-Clinical Diagnostics'** Vitros 5.1Fs.

According to Dr. Song, the TLA line for routine chemistry and serology is run by five FTEs. This staff covers reception, urine chemistry, HbA1c, immunoassay, and serology. Total staff in the laboratory is: two M.D./Ph.D.s, two residents, one registered nurse, 35 full time techs, and seven part time techs. To handle outpatient phlebotomy, there are nine phlebotomists on Monday and five for Tuesday through Friday. As a final note, this hospital of 833 beds has four anatomic pathologists.

The laboratory occupies 1,711 square meters, or 18,400 square feet. This hospital has a paperless information system and another unique feature. Physicians are equipped with PDAs. These cannot yet receive lab test data, but the PDAs are used as cell phones.

Reference Testing Lab Firm

The third laboratory on the tour was **Green Cross Reference Laboratories**. This is a commercial laboratory company. It was founded in 1992 and it provides reference and esoteric test to hospitals and outpatient clinics in Korea.

In many respects, Green Cross is the same business model as **ARUP Laboratories** and **Mayo Medical Laboratories** in the United States. Approximately 80% of its specimens are referred by hospitals and academic center laboratories. The remaining 20% comes from clinics.

Green Cross operates 20 branches in Korea. In 1995, it earned accreditation by the **College of American Pathologists** (CAP). In 1999, it was certified as ISO-9000 compliant.

Green Cross established an Institute for Molecular Genetics in 1997. It also has an Institute of Metabolism for newborn screening and is expanding into TDM (therapeutic drug monitoring) and metabolic analysis.

New Lab Built In 2004

Host for our tour was H. R. Moon, M.D., CEO of Green Cross Reference Laboratory. Dr. Moon discussed the history of the company, noting that the new laboratory was built in 2004 to expand capacity, improve turnaround time, and support ongoing cost reduction initiatives.

Green Cross has 300 employees and 10 physicians. The laboratory occupies several floors in a new building of 9,900 square meters (about 106,000 square feet). The lab runs 24/7. On a daily basis, it handles about 10,000 samples and performs 30,000 tests.

"The decision to install laboratory automation was due to increased growth in specimen volumes," stated Eun Hee Lee, M.D., Ph.D., Vice President at Green Cross. "Our laboratory had reached maximum capacity and we projected continued growth."

Green Cross opted for the Bayer ADVIA Lab Cell solution. It has sample managers, three chemistry analyzers (ADVIA 1650 and ADVIA 2400) and three immunoassay analyzers (ADVIA Centaur 3).

"There have been several benefits from our new automation," observed Lee. "The number of tests per FTE jumped 28%, from 1,250 tests per FTE

Fifth Annual Conference on Laboratory Automation and Robotics—Site Visit to Green Cross Reference Laboratories in Seoul, Korea: From Left: Eddie Ang Han San, Ph.D., of Singapore Ministry of Health; H.R. Moon, M.D., CEO of Green Cross Reference Laboratory; Jin Q. Kim, M.D., Ph.D., Conference Chair and Chairman and Professor, Department of Laboratory Medicine at Seoul National University Hospital; Charles D. Hawker, M.D., Ph.D. of ARUP Laboratories; Robin A. Felder, Ph.D, of the University of Virginia Health System; Robert L. Michel of THE DARK REPORT; Alan Lloyd, MB.ChB, of Sonic Healthcare Ltd. in Sydney, Australia.

to 1,600 tests per FTE. Because this system operates from single primary tubes, the number of tubes has been reduced by 40%."

Overall, these three site visits provided fascinating insights into the similiarities and differences between laboratories in South Korea and the United States. The hospital facilities we toured were quite new. Laboratories are well-designed and equipped with state-of-the-art instruments and equipment.

These laboratories would look familiar to any laboratorian working in the United States. Test menus are similiar, instrumentation is similar, and basic work flows within the laboratory are similar. Because of extensive use of automation, these laboratories are highly efficient with labor.

The most interesting difference may be that healthcare in South Korea is organized around a system that integrates hospitals and outpatient clinics. This places hospital labs at the center of diagnostic testing. It also means that laboratory testing is a community-based resource, since there are no commercial lab competitors in Korea.

What remains unanswered after this day of laboratory tours is a simple question: are the highly-automated laboratories in Korea equal or better than their American counterparts in two areas: lowest average cost per test and added-value to clinicians? Maybe a side-by-side case study at a future *Executive War College* between a Korean lab and an American lab would reveal an answer! TDR

Lab Automation Pioneer Assesses Outcomes

Venerated lab automation figure makes surprising declaration

CEO SUMMARY: ***Debate has dogged the subject of laboratory automation since its earliest days. That was true during the early 1990s in Japan. It was true in Canada and the United States throughout the 1990s. It is still true in this decade. That is why it was startling to hear a founding father of clinical laboratory automation declare that automation had taken Japan's laboratories down a "harmful" path.***

By Robert L. Michel

PROBABLY THE SINGLE BIGGEST SURPRISE of the "Fifth International Conference on Laboratory Automation and Robotics" was the moment when one of laboratory automation's most venerated pioneers raised doubts about the long-term value of laboratory automation.

That moment came near the end of the presentation made by Jutaro Tadano, M.D., Ph.D. Dr. Tadano was a member of the so-called "Gang of Four," the name given to the four Japanese pathologists who were first to design and introduce automated systems into their laboratories during the early 1980s. Currently he is Managing Director of the **OGATA Institute for Medical & Chemical Research**, located in Tokyo, Japan

Dr. Tadano's presentation was titled "The History of Laboratory Automation in Japan: The Endeavors and Achievements." He was summarizing the evolution of laboratory automation in that country and discussing the outcomes which resulted from widespread introduction of automation into laboratories throughout Japan.

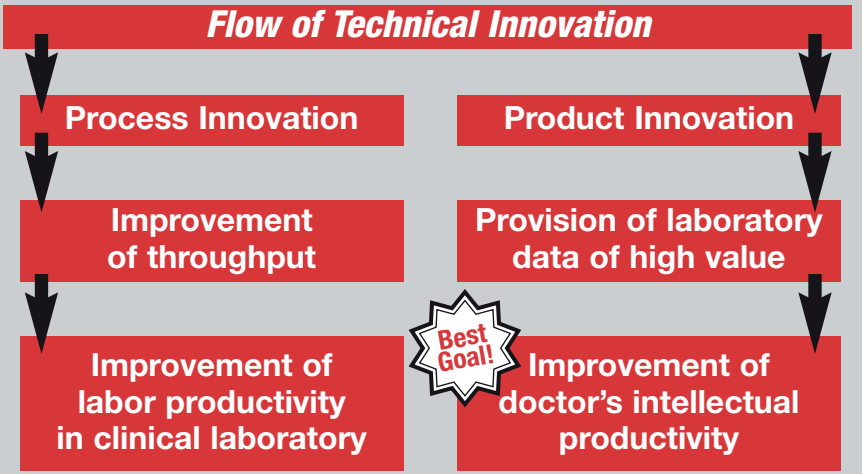
"Today, as I look back, it can be said that the Gang of Four had a harmful effect on laboratories in Japan because of their development of TLA (Total Laboratory Automation)," declared Dr. Tadano. "It's been harmful because these automated systems were developed and implemented with one primary goal in mind: to drive improvement in laboratory productivity. Laboratories did not place equal or greater focus on physicians and patients."

Emphasis On Process

Tadano was very specific in defining the harm laboratory automation had done to laboratories in Japan. "Process innovation definitely increased the sample throughput in laboratories across Japan and caused a cost reduction in specimens handled," he noted. "However, this brought unintended, negative consequences for laboratories.

"Automation did increase productivity [and lower operational costs], but this allowed the national health system

Dr. Tadano's Advice for Clinical Laboratories



REPRODUCED ABOVE IS THE SLIDE presented by Jutaro Tadano, M.D., Ph.D. during his talk at the Fifth International Conference on Laboratory Automation and Robotics, held in Seoul, Korea on April 13-14, 2006. In discussing the primary goals for technological innovation in clinical laboratories, Dr. Tadano observed that, during the past 25 years, new technologies were applied primarily to improving the operational productivity of clinical laboratories (the channel on the left of the slide). Dr. Tadano stated this proved "harmful" because it allowed healthcare payers to lower laboratory reimbursement and hospitals to significantly reduce laboratory budgets.

Based on these developments, Dr. Tadano now recommends that clinical laboratories should apply new technology to a different goal: improving the value of laboratory information to physicians. This is how laboratories can add value to the healthcare system and generate the increased levels of funding needed to sustain ongoing laboratory operations and to encourage further technology innovation.

in Japan to reduce the amount of reimbursement paid for laboratory testing services," explained Dr. Tadano. "Over the years, the national health service reduced reimbursement by amounts proportional to the lowered costs that resulted from automation."

Dr. Tadano provided a specific example of the negative financial effect. "In 1986, reimbursement for the 10 items in a chemistry panel was 4,800 yen ($44.00). By the year 2006, this reimbursement had dropped to 1,300 yen ($12.00)," he said. "That is a 73% reduction!"

According to Dr. Tadano, the emphasis by laboratories on process innovation and automation to lower the direct cost of handling and testing specimens caused another damaging outcome to laboratories. "Because of the large scale cost reduction achieved by laboratories during the past 25 years, hospitals cut the laboratory budget," he stated.

"Collectively, these actions have been harmful," continued Dr. Tadano. "Lowered reimbursement by the national health service and reduced laboratory budgets within hospitals

are starving laboratories in this country of capital."

Dr. Tadano's next statement was direct, even blunt. "Because of these factors," he declared, "many laboratories in Japan are in the process of decline!"

This is a remarkable declaration from an individual who lived a life committed to process innovation and using laboratory automation to improve the productivity, quality, and overall performance of laboratory automation. But Dr. Tadano had a larger purpose in pointing out why he believed the drive to automate laboratories in Japan had missed the mark.

"Clinical laboratories can apply technical innovations down either of two paths," noted Tadano. "Technical innovation can be used to streamline work processes. This triggers improvement in throughput and improvement in the productivity of labor in the clinical laboratory.

Creating Added Value

"The other path for technical innovation is to use this technology to improve products," he continued. "These products create laboratory data of high value—which directly improve the intellectual productivity of doctors."

With these remarks, Dr. Tadano drew a bold line between the use of technology to streamline internal laboratory work processes and the use of technology to improve the ability of clinical laboratories to produce high-value lab information of the type that helps physicians deliver high-quality healthcare outcomes to their patients. *(See chart on previous page.)*

"The goal of clinical laboratories should be to use product innovation to improve the intellectual productivity of physicians," explained Dr. Tadano. "We should be changing laboratory data from a [simple] signal to information that has high value to the physician.

"This creates a different mindset for the clinical laboratory," he added. "It calls for the laboratory to be a supplier of medical information. This should be the new emphasis for clinical laboratories."

New Mindset For Labs

This statement clearly demonstrates the evolution in Dr. Tadano's thinking. Whereas he spent most of his career viewing one primary goal of laboratory management to be the improvement of operational work flow and process innovation, he now recognizes that this mindset was counterproductive to the laboratory profession over the long term.

With the perspective of 25 years experience, Dr. Tadano now urges laboratories to recognize the importance of directing innovation primarily at delivering higher value information to the physician. Innovation of this type will reframe and enhance the contribution clinical laboratories make to the healthcare system.

Dr. Tadano's presentation was a remarkable acknowledgement that, regardless of the significant benefits that resulted from an intense drive to cut operational costs, improve productivity, and reduce errors in the work processes of clinical laboratories, clinical laboratories in Japan missed the opportunity to contribute even more value to physicians and patients.

Valuable Insights

The informed opinions of Jutaro Tadano, M.D., Ph.D. deserve a more detailed hearing. His experience and insights into the value of laboratory automation and the operation of clinical laboratories is both unique and invaluable. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Lots of news unfolding across the lab industry. Here's a round-up of recent and noteworthy items:

NEW VENTURES

• Persistent rumors indicate that a new national anatomic pathology company is in formation. Likely to be involved is James New, former CEO of **AmeriPath, Inc.** during its formative years and through that company's sale to **Welsh Carson Anderson & Stowe** in early 2003. *(See TDR, March 3, 2003.)* Another name linked to this nascent enterprise is Martin J. Stefanelli, who was part of the executive team at AmeriPath with New. A funding package totaling $300 million is expected to launch the business, which apparently intends to purchase only pathology groups which operate outside of hospitals. If $300 million is available for acquisitions, this new business is likely to prove disruptive to community hospital-based pathology practices.

• There's a new laboratory consulting company in the marketplace. Called **Nexus Global Solutions, Inc.**, it will offer "strategic solutions for the diagnostic market," including laboratories. Based in Dallas, Texas, the new firm has three managing partners: Tim Baker, Brian Jackson, and Andrew Williams. In recent years, these individuals have provided Six Sigma and other consulting services to clinical laboratories.

TERMINATED VENTURES

• When the 300 employees of **Universal Diagnostic Laboratories** in New York, New York, came to work on Monday, April 10, they found their laboratory closed and out of business. This laboratory had been acquired in December 2004 by a consortium that included laboratory executives Craig Dawson and Len Poikey, Ph.D., and venture capital groups. *(See TDR, February 21, 2005.)* The deal was probably ill-advised from the start. Investors dismissed Dawson and Poikey from the lab earlier this year. Not finding a satisfactory buyer, they closed the lab company outright and are liquidating its assets.

• Another sad lab industry business story may be concluded soon. Leaks from inside **Quest Diagnostics Incorporated** suggest that the company is preparing to close **Nichols Institute Diagnostics**. This troubled business unit, which stopped selling its diagnostic kits last summer after FDA recall notices, represented approximately $40 million in revenues. *(See TDR, July 11, 2005.)*

SOLD VENTURES

• Laboratories with proprietary diagnostic technology and niche markets continue to attract big dollars. Last month, **Fisher Scientific International, Inc.** of Hampton, New Hampshire, announced agreements to acquire **Athena Diagnostics Inc.** of Worcester, Massachusetts (neurology tests) and purchase a minority interest in **Nanogen Inc.** of San Diego, California (microarrays and reagents). Fisher will pay $283 million and $15 million, respectively, for the Athena and Nanogen interests.

RETIREMENTS

• In Vorhees, New Jersey, long-time pathology and laboratory consultant Al Giles, President of **Anodyne Green**, has announced his retirement.

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 22, 2006.